K032135

510(k) Summary
Site~Rite IV Ultrasound Scanner

Common/Classification Name: Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560

Dymax Corporation
271 Kappa Drive, Pittsburgh, PA 15238
(412)963-6884 – (412)963-6179 (Fax)

JUL 21 2003

Contact: Charles Morreale; Prepared: June 30, 2003

A. LEGALLY MARKETED PREDICATE DEVICES

The Site~Rite IV Ultrasound Scanner is substantially equivalent to the Site~Rite 3 Ultrasound Scanner (K993624) and the Dymax Site~Rite II Ultrasound System (cleared as the Dymax Plus 1 Scanner, K862127).

B. DEVICE DESCRIPTION

The Site-Rite IV pulsed echo ultrasound system is a lightweight, low-output, portable, real-time, B-mode, ultrasound scanner designed primarily to assist clinicians in gaining vascular access to major veins, arteries and organs. It is a unique scanner that offers high resolution imaging to the depth of 18 cm. Site-Rite is portable and thus easy to use at the bedside and in a variety of clinical settings: intensive care units, emergency rooms, operating rooms, angiography suites, catheterization laboratories, etc.

The Site-Rite IV ultrasound scanner can be operated on battery or AC power. It utilizes only proprietary probes manufactured and currently marketed by Dymax, with frequencies ranging from 3.5 MHz to 9.0 MHz. Image depth depends on the choice of probe and ranges from a minimum of 0.5 cm with the 9.0 MHz probe to a maximum of 18 cm with the 3.5 MHz probe.

The disposable items, supplied in sterile packs, are currently marketed products.

C. INTENDED USE

The Site~Rite IV ultrasound system with associated probes and accessories provide ultrasound imaging of vascular structures, various organs, and structures of the body. Ultrasound guidance for placement of needles and catheters in these structures or organs may also be performed. The ultrasound guidance may occur either intraoperatively or percutaneously.

The Site~Rite IV is not intended for opthalmic applications.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The Site~Rite IV Ultrasound Scanner has identical indications for use as the Site~Rite 3 Ultrasound System.

The technological characteristics are similar to the predicate devices except that the electronics design has been updated from the Site~Rite 3 Ultrasound System. The Site~Rite IV Ultrasound System has been designed for manufacturability and improved reliability. The transducers, however, are unchanged from the currently marketed products.

The differences in technological characteristics do not raise new types of questions of safety and effectiveness. There are standard methods for accessing safety and performance, primarily through the methods spelled out in the FDA guidance. Performance data are presented in the 510(k) and these data demonstrate equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The primary difference in the Site~Rite IV Ultrasound System and the Site~Rite II Ultrasound System is that the older Site~Rite II has a generator with an analog design, whereas the Site~Rite IV Ultrasound System and the Site~Rite 3 Ultrasound Systems are digital in design.

F. TESTING

Testing was carried out to address electrical safety, electromagnetic emissions, and acoustic output. Data from this testing demonstrate equivalence with the predicate devices and meets the recommendations of the FDA document, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.*

Clinical studies carried out using the Site~Rite 2 device, which uses the same transducers and image processing algorithms, has shown the usefulness of the Site~Rite for needle placement in a number of different vascular and non-vascular applications. These studies are summarized and reports are included in the 510(k).

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2003

Dymax Corporation
% Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH PA 19462-1298

Re: K032135
Trade Name: Site~Rite IV Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: July 10, 2003
Received: July 11, 2003

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Site~Rite IV Ultrasound System, as described in your premarket notification:

Transducer Model Number

3.5 MHz
5.0 MHz
7.5 MHz
9.0 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

STATEMENT OF INDICATION FOR USE

510(k) Number (if known): K032135

Device Name: Site~Rite IV Ultrasound System

Indications For Use:

The Site~Rite IV Ultrasound System with associated probes and accessories provide ultrasound imaging of vascular structures, various organs, and structures of the body. Ultrasound guidance for placement of needles and catheters in these structures or organs may also be performed. The ultrasound guidance may occur either intraoperatively or percutaneously.

The Site~Rite IV Ultrasound System is not intended for ophthalmic applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032135

Prescription Use V OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

3.5 MHz Probe

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (specify)		P								
Intraoperative Neurological		P								
Pediatric										
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac		P								
Transesophageal		P								
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: Intraoperative – Epiatoric Scanning; Small Organ – Breast, Testes, Thyroid, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use (Per 21 CFR 801.109)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032135

5.0 MHz Probe

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (specify)		P								
Intraoperative Neurological		P								
Pediatric										
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac		P								
Transesophageal		P								
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: Intraoperative – Epiatoric Scanning; Small Organ – Breast, Testes, Thyroid, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)

Division of Reproductive, **Abdominal,**

a[illegible]nological Devices

51[illegible] Number K032135

7.5 MHz Probe

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (specify)		P								
Intraoperative Neurological										
Pediatric		P								
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: Intraoperative – Epiatoric Scanning; Small Organ – Breast, Testes, Thyroid, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032135

9.0 MHz Probe

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (specify)		P								
Intraoperative Neurological										
Pediatric		P								
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: Intraoperative – Epiatoric Scanning; Small Organ – Breast, Testes, Thyroid, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Neurological Devices

510(k) Number K032135